UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON

IN RE: SERZONE
PRODUCTS LIABILITY LITIGATION

MDL NO. 1477

THIS DOCUMENT RELATES TO ALL CASES

MEMORANDUM OPINION AND ORDER

Currently pending before the court are four areas of disputed discovery related to Plaintiffs' First Set of Requests for Production of Documents to Defendants ("RFP"). The parties have thoroughly briefed the issues, and the court heard oral argument on April 11, 2003. The court has carefully considered the arguments of the parties in their written submissions and at oral argument and makes the following findings with respect to the outstanding discovery disputes.

I. Document Destruction Policies (RFP # 16).

RFP # 16 and Defendant Bristol-Myers Squibb Company's ("BMS") response are as follows:

> REQUEST NO. 16:
>
> Each of your document retention or document destruction policies in effect for the years January 1, 1987 through 2002 and all documents that discuss or refer thereto.
>
> Response. In addition to the general objections numbers 1, 2, 3, 4, 5, 7, 8, 10, 11, 12, and 13, BMS objects to this request on the grounds that it is vague, ambiguous, and undefined with respect to the phrase "all documents

> that discuss or refer thereto". BMS further states that unless and until plaintiffs make a specific showing that some particular document has been improperly destroyed, its document retention and/or document destruction policies bear no relevance to the claims or defenses raised in this litigation. BMS further states that only its current document retention policies would be applicable to this litigation. Subject to and without waiving its objections, BMS states that it maintains comprehensive document retention procedures by department, group and document type documenting hundreds of different procedures and therefore, only if plaintiffs provide greater specificity as to the particular type of relevant documents for which they seek retention procedures will BMS be able to search for and identify any appropriate document retention procedures.

Plaintiffs argue that BMS has not met its burden of showing facts sufficient to demonstrate the time and expense involved in responding to the request. (Plaintiffs' Memorandum Regarding Outstanding Discovery Issues ("P.s' Br."), p. 6.)

BMS argues that until Plaintiffs provide a reasonable showing that some document or documents were improperly destroyed, Plaintiffs lack sufficient justification to compel the production of document retention policies. (Defendant Bristol-Myers Squibb Company's Brief in Support of its Objections to Plaintiffs' First Request for Production and Request for Protective Order ("D.'s Br."), p. 10.) BMS contends that it maintains hundreds of comprehensive document retention procedures or policies that are broken down by department, group and document type. These policies have no relationship to Serzone® and, as a result, have no bearing on this litigation. BMS further argues that the time frame suggested by Plaintiffs, 1987 to the present, is

inappropriate because Serzone® was not launched until 1995 in the United States, most Plaintiffs did not use the product until well after 1995 and none of the MDL claims was filed prior to March 2002. (D.'s Br., pp. 11-12.) BMS contends that at most, only those document retention policies in effect at the time this litigation commenced would be applicable since BMS suspended the operation of these policies in March 2002, when it directed that all documents which might be relevant to this litigation be maintained. Finally, BMS states that if Plaintiffs had questions about the 2002 retention policies applicable to a specific document, they would attempt to locate and produce the specific document retention policy. (D.'s Br., p. 12.)

The court finds that, as to BMS's retention of documents in general or Serzone®-related documents in particular, as the record stands today, Plaintiffs' request is overly broad and seeks the production of documents that are only tangentially relevant to the claim or defense of any party, as required by Rule 26(b)(1) of the Federal Rules of Civil Procedure. In the event Plaintiffs uncover evidence of document destruction through deposition testimony or otherwise, the court will revisit this issue. Accordingly, it is hereby **ORDERED** that to the extent Plaintiffs seek to compel a response to RFP # 16, Plaintiffs' request is **DENIED** without prejudice.

II. General Corporate Organizational Charts, etc. (RFP # 18).

The relevant portions of RFP # 18 and BMS's response are as follows:

> REQUEST NO. 18:
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> For each year Defendants designed, tested, manufactured, sold, marketed, licensed or distributed Serzone, please provide every document relating to, referring to or containing:
> a. general corporate organizational charts;
> b. sales department organizational charts;
> c. marketing department organizational charts;
> d. research and development department organizational charts;
> * * *
>
> Response. In addition to general objections numbers 1, 2, 3, 5, 6, 7, 8, 10, 11, 12 and 13, BMS objects to this request on the grounds that it is vague, ambiguous, and undefined with respect to the phrase "every document relating to, referring to or containing". BMS further states that the organizational charts for each of its many departments bear no relevance to the claims or defenses raised in this litigation, particularly when considering the overly broad time period referenced and the lack of a specific subject matter. BMS further states that its organizational charts generally are not broken down by product and would not assist plaintiffs in obtaining relevant discovery or in identifying potential witnesses, therefore, the burden associated with the collection and production of such documents far outweighs any benefit derived from same.

Plaintiffs argue that BMS has not met its burden of showing facts sufficient to demonstrate the time and expense involved in responding to the request. (P.s' Br., p. 7.) Plaintiffs assert that without this information, they will be forced to "embark on an unnecessary fishing expedition, involving the taking of potentially hundreds of depositions, in order to simply identify

key players and persons with relevant information." (P.s' Br., p. 8.)

BMS argues that the request bears no relevance to the claims or defenses raised in the litigation. (D.'s Br., p. 12.) BMS's organizational charts are not broken down by product, and, therefore, offer no guidance in ascertaining the names of employees who were involved with Serzone®. (D.'s Br., p. 13.) In addition, BMS contends that the time frame sought by Plaintiffs, from the year Serzone® was first developed through the present, is inappropriate in light of the fact that Serzone® was not launched in the United States until 1995, most plaintiffs did not use the product until much later and none of the MDL claims was filed prior to March 2002. BMS states that the charts are updated periodically as changes are made within the corporate structure, and, it only maintains current versions of each chart. While employees of BMS may have randomly kept old organization charts, BMS does not have an official policy for retaining these. (D.'s Br., p. 14.) Finally, BMS states that Plaintiffs should be able to identify key players through other discovery already produced. (D.'s Br., p. 15.)

As with the court's finding as to RFP # 16, the court finds that RFP # 18 is overly broad and seeks the production of documents that are not even tangentially relevant to the claim or defense of any party, as required by Rule 26(b)(1) of the Federal

Rules of Civil Procedure. The court appreciates Plaintiffs' interest in identifying those individuals at BMS who were involved with Serzone® during the relevant time period. To that end, Plaintiffs advised the court that they have propounded an interrogatory due next week, which seeks this very type of information. In addition, BMS agreed at oral argument to produce to Plaintiffs, its current organization chart.

With respect to depositions in general, the court encouraged the parties to work together to compose a deposition schedule. In devising this schedule, the parties should take into consideration the geographic location of the witnesses, the convenience of the witnesses, parties and lawyers and the subject matter of each deposition and the logical order of the depositions based on that subject matter. With respect to those witnesses who are current or former BMS employees who possess relevant information about Serzone®, the court suggested that prior to these depositions, the parties should informally exchange information about the witness's understanding of (1) to whom the witness reported to at BMS; (2) with whom the witness worked during the critical times; and (3) other relevant areas related to the witness's background. The court advised the parties that if necessary, it is available to assist them in this regard. Accordingly, it is hereby **ORDERED** that to the extent Plaintiffs seek to compel a response to RFP # 18, Plaintiffs' request is **DENIED** without prejudice.

III. Trade Organization Codes of Conduct Re: Marketing or Labeling (RFP # 27).

REQUEST NO. 27:

> Every document relating to, referring to or containing any codes of conduct or ethical standards with respect to the marketing or labeling of drug products that were promulgated or adopted by any trade organization of which you were a member between January 1, 1987 and 2002.
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> Response. In addition to general objections numbers 1, 2, 3, 4, 5, 7, 8, 10, 11, 12 and 13, BMS objects to this request on the grounds that it is vague, ambiguous, and undefined with respect to the phrase "relating to, referring to or containing". BMS further states that codes of conduct and ethical standards, without further specificity, bear no relevance to the claims or defenses raised in this litigation. BMS further states that a trade organization's code of conduct or ethical standard with respect to the marketing or labeling of a drug, if such codes exist, would be equally available to plaintiffs and therefore, BMS should not be compelled to search for and/or produce same and that plaintiffs can and should obtain such documents directly from the trade organization.

Plaintiffs argue that "[t]he extent to which BMS subscribes to and does not follow (or does not subscribe to) industry ethical standards about the marketing of prescription drugs is very relevant in this negligence case." (P.s' Br., p. 8.)

BMS asserts that the documents requested by Plaintiffs bear no relevance to the claims or defenses raised in the litigation. BMS contends that "[t]hese trade organizations have no control over BMS and BMS has no control over these trade organizations. Further, the mere fact that a company belongs to an organization or association does not subject it to that organization's beliefs or

tenets." (D.'s Br., p. 15.) BMS points out that "Plaintiffs requested and received the codes of conduct and ethical standards promulgated by BMS, none of which are specifically applicable to the marketing or labeling of prescription drug product." (D.'s Br., pp. 14-15.) BMS further asserts that the request is not limited to Serzone®, to prescription medications or to anything relevant in this litigation. Finally, BMS avers that Plaintiffs can obtain this information on their own. (D.'s Br., p. 16.)

The court finds that RFP # 27 is overly broad. The court directed BMS to produce to Plaintiffs, a list of trade organizations to which it belonged from 1995 to the present. Accordingly, it is hereby **ORDERED** that to the extent Plaintiffs seek to compel a response to RFP # 27, Plaintiffs' request is **DENIED.**

IV. Documents Maintained in Foreign Jurisdictions.

Many of Plaintiffs' requests for production generally seek the production of foreign documents, while others more explicitly seek such production. Plaintiffs assert that the safety of Serzone® is the central issue in this matter and, foreign documents pertaining to Serzone® are relevant in the instant matter because (1) BMS has withdrawn Nefazodone, Serzone®'s European counterpart, from the market throughout Europe; and (2) foreign regulatory agencies have been actively investigating the safety of Serzone®. (P.s' Br., p. 9.) Plaintiffs point out that similar discovery was allowed in the

Propulsid litigation. Plaintiffs assert that BMS's contention that the documents are not relevant because of different safety standards in Europe is unpersuasive. (P.s' Br., p. 10.) Finally, Plaintiffs argue that BMS's self-imposed limitation that it will only produce relevant and responsive documents from its international affiliates that are in the control and custody of BMS in the United States violates Rule 34's requirement that a party produce documents in its possession, custody or control. (P.s' Br., p. 11.)

BMS argues that it is not engaged in collection of documents outside the United States for purposes of litigation and that production of documents located in foreign countries poses a substantial burden. (D.'s Br., pp. 21-24.) BMS contends that Nefazodone has been sold in approximately 40 countries and, many of these jurisdictions have completely different regulatory requirements and standards that control the manufacture, labeling, marketing, sale and distribution of the product. (D.'s Br., p. 17.) Despite this, BMS represents that documents related to the testing and study of Nefazodone, Nefazodone adverse event reporting and other documents are created or maintained in the United States and those documents or the relevant information contained in those documents have been or will shortly be produced to Plaintiffs. Documents transmitted to BMS's Global Pharmacovigilance and Labeling Group, which is located in the United States, also have

been or will be produced to Plaintiffs. (D.'s Br., p. 19.) BMS explained at oral argument that its Global Pharmacovigilance and Labeling Group is responsible for the safety of all of BMS's products worldwide and possesses safety updates, adverse event reports and communications to the Federal Drug Administration, both with respect to Serzone® and Nefazodone.

Until Plaintiffs have had an opportunity to review the documents produced by BMS, particularly those from BMS's Global Pharmacovigilance and Labeling Group and other foreign documents produced or soon to be produced by BMS, a ruling on Plaintiffs' motion to compel the production of foreign documents potentially responsive to a number of the discovery requests propounded by Plaintiffs is premature. Once Plaintiffs have had a chance to review documents (which Plaintiffs' counsel indicated will occur within the next month) and in the event Plaintiffs identify additional foreign documents they wish to have, the court expects the parties to work together and, where impasse is reached, contact the court for guidance on or before **July 1, 2003**. Accordingly, it is hereby **ORDERED** that to the extent Plaintiffs seek to compel requests for production of documents located in foreign jurisdictions, Plaintiffs' request is premature and therefore, **DENIED** without prejudice.

As a final matter, at the hearing on these discovery disputes, the parties advised the court as to the progress of discovery. BMS

advised the court that none of the Plaintiff's Fact Sheets received to date is complete, that there are no verifications attached and that other Plaintiffs have yet to respond at all. The court advised the parties that while short (one or two week) extensions of the deadline for the completion of a particular Plaintiff's Fact Sheet is acceptable, longer extensions are not. The court expects Plaintiffs to work diligently to provide completed Fact Sheets in a timely manner. To that end, the court instructed Plaintiffs to designate a representative who will keep track of the progress of each Plaintiff's completion of the Fact Sheet and advise BMS when they inquire as to the status of any Plaintiff's Fact Sheet.

The court directs the Clerk to send a copy of this Memorandum Opinion and Order to Plaintiffs' Liaison Counsel and Defendant's Liaison Counsel and Judge Goodwin.

ENTER:

Mary E. Stanley

Mary E. Stanley
United States Magistrate Judge